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SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

LAU, JONATHAN S

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### ADVISORY ACTION

Applicant's Amendment AFTER FINAL, filed 02 Jan 2009, will be entered, as Applicant's Amendment AFTER FINAL does not raise new issues that would require further consideration and/or search, does not raise the issue of new matter, does place the application in better form for appeal by materially reducing or simplifying the issues for appeal, and does not present additional claims without canceling a corresponding number of finally rejected claims.

Continuation of 5.

Applicant's Amendment AFTER FINAL, filed 02 Jan 2009, with respect to claims 12, 14, 20 and 22 rejected under 35 USC 112, second paragraph as being indefinite has been fully considered and is persuasive, as amended claims 12 and 20 are definite in what is meant to be treated and claims 14 and 22 are canceled.

This rejection has been **withdrawn**.

Applicant's Amendment AFTER FINAL, filed 02 Jan 2009, with respect to claims 1-3, 6-17 and 19-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Bussolari et al. (US Patent Application Publication US 2003/0045553, published 6 Mar 2003, of record) has been fully considered and is persuasive with regard to claims 14 and 22, as claims 14 and 22 are canceled.

This rejection with regard to claims 14 and 22 has been **withdrawn**. This rejection with regard to claims 1-3, 6-13, 15-17 and 19-21 is **maintained**.

Continuation of 11.

Applicant's Amendment AFTER FINAL is entered as detailed above. Applicant's Remarks, filed 02 Jan 2009, in view of Applicant's Amendment AFTER FINAL have been fully considered and found not to be persuasive regarding now amended claims 1-3, 6-13, 15-17 and 19-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Bussolari et al. (US Patent Application Publication US 2003/0045553, published 6 Mar 2003, of record).

Applicant notes that intestinal absorption of glucose and reabsorption of glucose in a kidney, or renal glucose reabsorption are clearly different medical mechanisms. However, Bussolari et al. at page 5, paragraph 72 teaches that the absorption of glucose is by the action of sodium-glucose cotransporters (SGLT), the SGLT1 isoform of which is found in both intestinal and renal cells, suggesting a biochemically related mechanism of absorption. Bussolari et al. at page 5, paragraph 73 does teach suppressing renal reabsorption of glucose leads to urine glucose excretion, a clearly different medical result from intestinal absorption of glucose. However, interpreted broadly, to inhibit reabsorption of glucose is to decrease the action or function of reabsorption of glucose. This may be achieved by limiting the amount of glucose present, thereby decreasing the action of reabsorption of glucose due to this reduced amount of glucose available to be reabsorbed. Applicant provides evidence teaching

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that alpha-glucosidase inhibitors do not affect absorption of monosacharides such as glucose (Cecil Textbook of Medicine). However, this evidence also teaches administration of alpha-glucosidase inhibitors "resulted in a small, but clinically meaningful reduction in glycosylated hemoglobin levels", providing guidance for the medical result of a small but significant reduction in the amount of glucose present, and the accordingly a reduction of actions associated with the intestinal absorption and renal reabsorption of glucose due to this reduction in the amount of glucose present. Relying on Applicant's translation of previously submitted document D, it is noted that the alpha-glucosidase inhibitor voglibose results in one example of absorption inhibition of the disaccharide sucrose of only about 5%, whereas the blood sugar level decreases by 20% and examples of decrease in blood sugar level with 0.1g and 0g inhibition of sucrose absorption. Applicant concludes based on the evidence of document D that the main action of the alpha-glucosidase inhibitor is to delay absorption of glucose. However, as recited above, this small reduction in the amount of glucose is interpreted broadly to lead to a small reduction in the action of reabsorption of glucose. That this inhibition, or decrease in the action, of reabsorption of glucose of is not the main mode of action of an alpha-glucosidase inhibitor does not negate it being, broadly interpreted, a resultant biophysical effect of the compound.

Applicant acknowledges that the comparison provided in the Office Action mailed 01 Aug 2008 is based on the maximum before loading and the minimum after loading. As provided by Applicant in Table B, analysis of the data shows range wherein the

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effects of voglibose and fenofibrate in combination is notably different from the effects of voglibose alone or the effect of fenofibrate alone. However, this comparison was provided to show that the provided data and therefore the scope of the claims encompasses a range wherein the effects of voglibose and the effect of fenofibrate is roughly additive. Therefore this data is not clear and convincing evidence of an unexpected advantage commensurate in scope with the claims.

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